K080682

Handpiece Headquarters
A HENRY SCHEIN COMPANY

510(K) SUMMARY:

SEP 11 2008

AIR-POWERED HANDPIECE
MODELS: HENRY SCHEIN/ HHC/ SCORE Canister Handpiece.
(Identical Handpiece/ 3 difference labels)

510K

a- Submitted by: HANDPIECE HEADQUARTERS
2284 N. GLASSELL ST. UNIT A. ORANGE, CA.92865
Tel. 714-685-3070 Fax. 714-921-1852

b- Contact person: Tina Steffanie-Oak
Tel. 717-335-7230, ext. 4150 Fax. 717-335-7240
Email: tina.steffanie-oak@henryschein.com

c- Date summary prepared: 03/06/08

d- Device Name:
Trade or Proprietary Name: HENRY SCHEIN Canister Handpiece

Common Name: Air-Power Dental Handpiece
Classification Name: Dental Handpiece and accessories
(21CFR 872.4200)
Class: I

Product Code: EFB "Handpiece, Air-powered, Dental"

e- Substantial Equivalency is claimed against the following device:

SUPER-AIR S: Standard, 400,000 rpm, Wrench Type Chuck
SUPER-AIR: Standard, 400,000 rpm, push button chuck.
Products of Peng Lim Enterprise Co., Ltd. (K062947)

f- Description of the device:

The canister handpiece is a complete dental handpiece that includes the turbine (push button & a screw type). The handpiece is fully functional and is being offered in a 4 hole version.

High pressured air directly impacts the blade pockets of the impeller through an air intake tube located inside the handpiece body, which causes the air turbine to rotate at a high speed. The dental cutting bur connects to the turbine's shank (spindle),

which rotates at the same speed as the impeller. Cooling water flows through an inlet water tube at high pressure and blows out at an angle near the dental cutting bur to reduce temperature at cutting area.

g- Statement of Intended Use:

This Handpiece is used by authorized persons in the practice of dentistry.

This Handpiece is intended for removing carious material, reducing hard tooth structures, cavity preparations, finishing tooth preparations, restorations and polishing teeth.

h- Safety and effectiveness of the device:

The canister handpiece is as safe and effective as the predicate device as cited above.

I – Conclusion:

Based on the information in the notification Handpiece Headquarters believes that this Canister Handpiece is substantially equivalent to the claimed predicate device. (SUPER-AIR S & SUPER-AIR U Handpiece Models manufacture by PENG LIM ENTERPRISE CO., Ltd.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2008

Ms. Tina Steffanie-Oak
Senior Regulatory Specialist
Handpiece Headquaters Incorporated
2284 North Glassell Street, Unit A
Orange, California 92856

Re: K080682
Trade/Device Name: Henry Schein Canister Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 9, 2008
Received: September 10, 2008

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080682

Device Name: Henry Schein Canister Handpiece

Indications for Use:

The Dental Handpiece is used by authorized persons in the practice of dentistry.

This Handpiece is intended for removing carious material, cavity preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080682